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Koh-Ichi Sakata

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

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DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,311	Applicant(s) SAKATA ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

1. Please note the Examiner of record has changed. Contact information is provided at the close of this Action.

2. Claims 1-11 are pending.

Claims 1-5, 9 and 10, drawn to non-elected inventions are not examined on the merits.

Claims 6, 7, and 11 have been amended.

Claims 6-8 and 11 are under examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in WIPO on June 4, 2003. It is noted, however, that applicant has not filed a certified copy of the PCT/JP2003/007079 application as required by 35 U.S.C. 119(b).

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The NEW MATTER rejection of claims 6-8 and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendments to the claims.

6. The rejection of claims 6-8 and 11 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 6-8, and 11 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in light of Applicants' amendments to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 6, 8 and 11 under 35 U.S.C. 102(b) as being anticipated by Ogawa et al. (EP 1184665A1, published March 6, 2002, as cited in a previous Office Action) is withdrawn in light of Applicants' arguments.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 6 and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Promega Notes Magazine 63: 7-9, 1997. Promega discloses a method quantitating DNA-depending protein kinase (DNA-PK) activity fom HeLa cell nuclear extracts using [gamma ⁻³²P] ATP. The said extract is from HeLa cells, cervical cells. The cervix is the lower, narrow portion of the uterus.

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13. Claims 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Finnie et al. (Proc. Natl. Acad. Sci. 92: 320-324, January 1995). Finnie discloses a method of measuring DNA-PK in mammalian cell extracts from HeLa cells and human 1BR cells using [γ -³²P] ATP and determining peptide phosphorylation by liquid scintillation counting, see page 321, Results section and Figures 1 and 2.

14. Claims 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Loong et al. (Oncogene 23: 5562-5566, published online June 7, 2004). Loong discloses a method of detecting DNA-PK activity in cells derived from a patient with breast cancer (LB0003), cells derived from a patient with cervix carcinoma (LB0004) and control cell lines, see page 5564, DNA-PK activity...section and Figure 3. "DNA-PK activity was assayed by measuring the phosphorylation of a biotinylated p53-derived peptide substrate (Promega SignaTECT DNA-Dependent Protein Kinase (DNA-PK) Assay System) by cell extracts in the presence or absence of calf-thymus DNA. Incorporation of γ -[³²P] into the peptide was analysed with a phosphorimager (confirmed by scintillation counting) and DNA-PK activity calculated with a correction for background kinase activity.", see caption of Figure 3 on page 5564.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 6-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Promega Notes Magazine 63: 7-9, 1997, and further in view of Finnie et al. (Proc. Natl. Acad. Sci. 92: 320-324, January 1995) and Moll et al. (Oncogene 18: 3114-3126, 1999). The teachings of the Promega Notes have been set forth in the 102(b) rejection. The Notes do not teach the disclosed method wherein the DNA-dependent protein kinase activity in cells derived for the test subject is compared to the kinase activity in cells from a healthy subject and the cells are lymphoid cells.

However, Finnie teaches a method of measuring DNA-PK in mammalian cell extracts from HeLa cells and human 1BR cells from healthy subjects, using [γ -³²P] ATP and determining peptide phosphorylation by liquid scintillation counting. Moll further describes DNA-PK expression in normal human lymphoid tissues, see Figure 2 and Table 2 on pages 3117 and 3119, as well as page 3118, Figure 3, Protein...section, respectively. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assay lymphoid cells, as well as compare DNA-PK activity in these cells and cells from healthy subjects to establish cancer susceptibility and treatment in regard to DNA-PK. One of ordinary skill in the art would have been motivated to assay all of these types of cells because the secondary

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references show results from several studies suggest DNA-PK, a "[p]rotein kinase [is a critical factor] in a variety of cellular functions including cell growth, development, and cell death.", see Promega Notes, Introduction.

17. Claims 6-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loong et al. (Oncogene 23: 5562-5566, published online June 7, 2004), and further in view of Moll et al. (Oncogene 18: 3114-3126, 1999). The teachings of Loong have been presented in the 102(b) rejection. Loong does not teach the disclosed method wherein the DNA-dependent protein kinase activity is tested in lymphoid cells.

However, Moll teaches DNA-PK expression in normal human lymphoid tissues, see Figure 2 and Table 2 on pages 3117 and 3119, as well as page 3118, Figure 3, Protein...section, respectively. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assay lymphoid cells, as well as compare DNA-PK activity in these cells and cells from healthy subjects to establish cancer susceptibility and treatment in regard to DNA-PK. One of ordinary skill in the art would have been motivated to assay all of these cell types because it is art known DNA-PK, a serine/threonine protein kinase critical in the processes of cellular regulation, cell growth, development, and cell death.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

29 September 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643